EMA/178722/2024

European Medicines Agency decision

P/0167/2024

of 6 May 2024

on the acceptance of a modification of an agreed paediatric investigation plan for beclometasone (dipropionate) / formoterol (fumarate dihydrate) / glycopyrronium bromide (Trimbow and associated names), (EMEA-001875-PIP02-18-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0179/2019 issued on 15 May 2019, decision P/0365/2019 issued on 7 November 2019, the decision P/0313/2020 issued on 14 August 2020 and the decision P/0094/2021 issued on 17 March 2021,

Having regard to the application submitted by Chiesi Farmaceutici S.p.A. on 15 December 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 March 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for beclometasone (dipropionate) / formoterol (fumarate dihydrate) / glycopyrronium bromide, (Trimbow and associated names), pressurised inhalation, solution, inhalation powder, inhalation use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, 43122 - Parma, Italy.

EMA/PDCO/3695/2024
Amsterdam, 22 March 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001875-PIP02-18-M04

Scope of the application

Active substance(s):

Beclometasone (dipropionate) / formoterol (fumarate dihydrate) / glycopyrronium bromide

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Pressurised inhalation, solution

Inhalation powder

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Chiesi Farmaceutici S.p.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Chiesi Farmaceutici S.p.A. submitted to the European Medicines Agency on 15 December 2023 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0179/2019 issued on 15 May 2019, decision P/0365/2019 issued on 7 November 2019, the decision P/0313/2020 issued on 14 August 2020 and the decision P/0094/2021 issued on 17 March 2021.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 22 January 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of asthma

The waiver applies to:

- the paediatric population from birth to less than 5 years of age;
- pressurised inhalation, solution; inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments;

and

- all subsets of the paediatric population from birth to less than 18 years of age;
- inhalation powder, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of asthma

2.1.1. Indication(s) targeted by the PIP

Treatment of asthma in patients not controlled with medium-high doses of inhaled corticosteroids and long-acting beta2-agonists

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 5 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Pressurised inhalation, solution

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (CLI-05993CB1-01)** Open label, non-randomised, single dose pharmacokinetic (PK)/pharmacodynamic (PD) study of beclometasone dipropionate,

	formoterol fumarate and glycopyrronium bromide (CHF 5993) in adolescent asthmatic patients 12 years to less than 18 years of age (and adult asthmatic patients). **Study 2 (CLI-05993AA5-06)** Double blind, parallel group, study to assess safety and efficacy of CHF 5993 versus fluticasone propionate / salmeterol xinafoate pMDI (Seretide 125 Evohaler) as comparator in adolescents from 12 years to less than 18 years of age with uncontrolled asthma. **Study 3 (CLI-05993AB5-01)** Double-blind randomised, crossover, active-controlled study to evaluate pharmacokinetics (PK), efficacy, safety and tolerability of CHF 5993 in children from 5 years to less than 12 years of age with uncontrolled asthma. **Study 4 (CLI-05993AB5-02)** Double-blind, randomised, parallel-group active controlled study to evaluate the efficacy and safety of CHF 5993 in children from 5 years to less than 12 years of age with uncontrolled asthma.
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long-term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2033
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of chronic obstructive pulmonary disease (COPD)

Authorised indication(s):

- Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or a combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist
  - Invented name(s): Trimbow and associated names
  - Authorised pharmaceutical form(s): Pressurised inhalation, solution (pressurised inhalation), Inhalation powder
  - Authorised route(s) of administration: Inhalation use
  - Authorised via centralised procedure

2. Treatment of asthma

Authorised indication(s):

- Maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year
  - Invented name(s): Trimbow and associated names
  - Authorised pharmaceutical form(s): Pressurised inhalation, solution (pressurised inhalation)
  - Authorised route(s) of administration: Inhalation use
  - Authorised via centralised procedure